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**Lorenzo**

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(54) **STEERABLE LOCKING CATHETER**

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See application file for complete search history.

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(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 389 days.

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(52) **U.S. Cl.**

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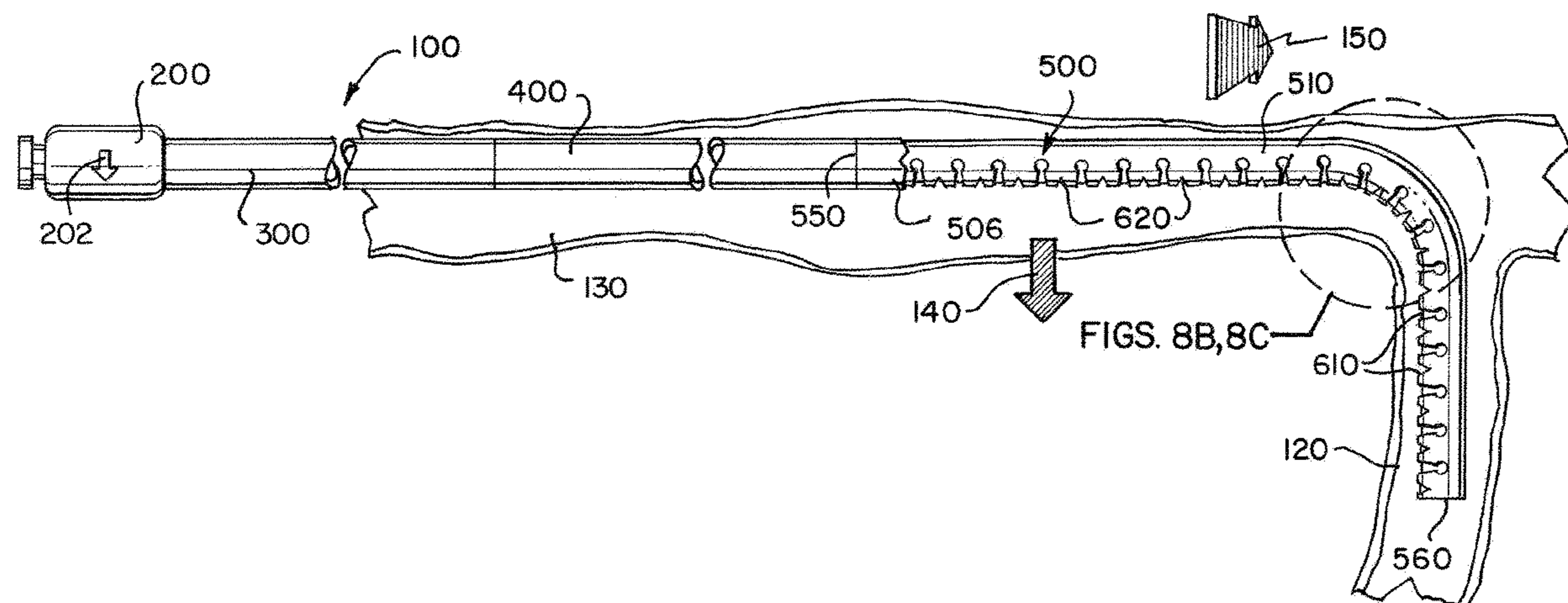
(57) **ABSTRACT**

The steerable catheter invention facilitates the tracking and selection of branch vessels, as well as provide the means for stiffening the catheter body across the tortuosity to anchor the catheter and minimize the potential for the catheter backing out of position while delivering interventional devices to the distal anatomy.

(58) **Field of Classification Search**

CPC ..... A61M 25/0138; A61M 25/0147; A61M 25/0054; A61M 25/0136; A61M

**20 Claims, 8 Drawing Sheets**



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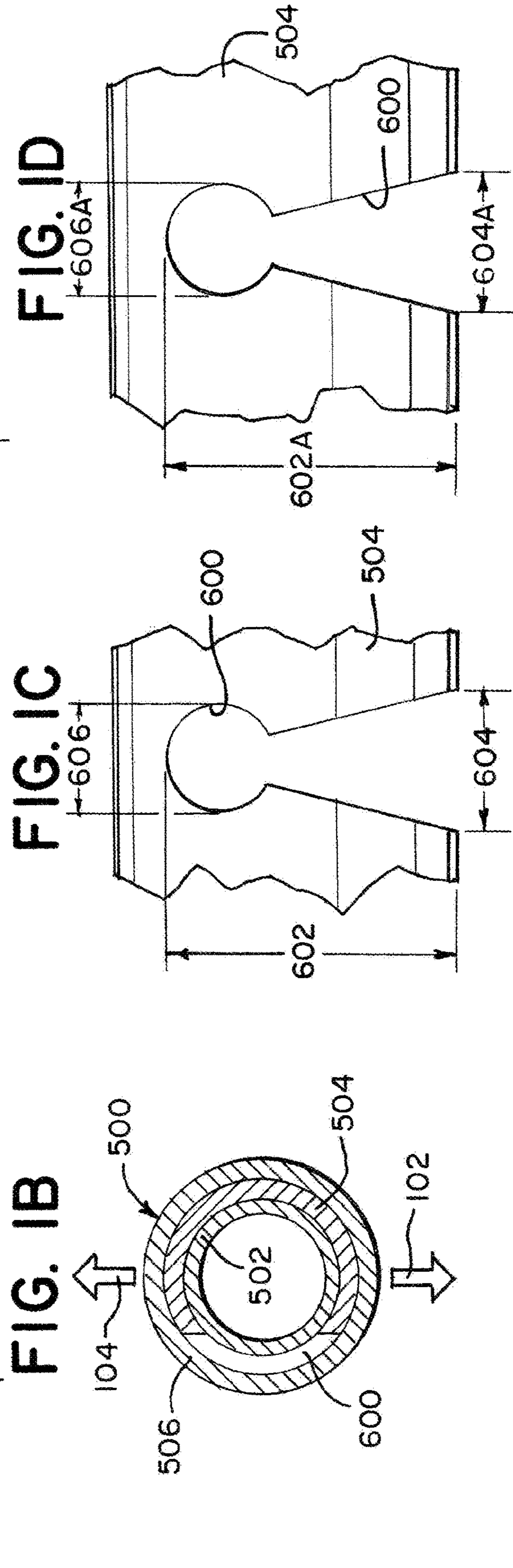
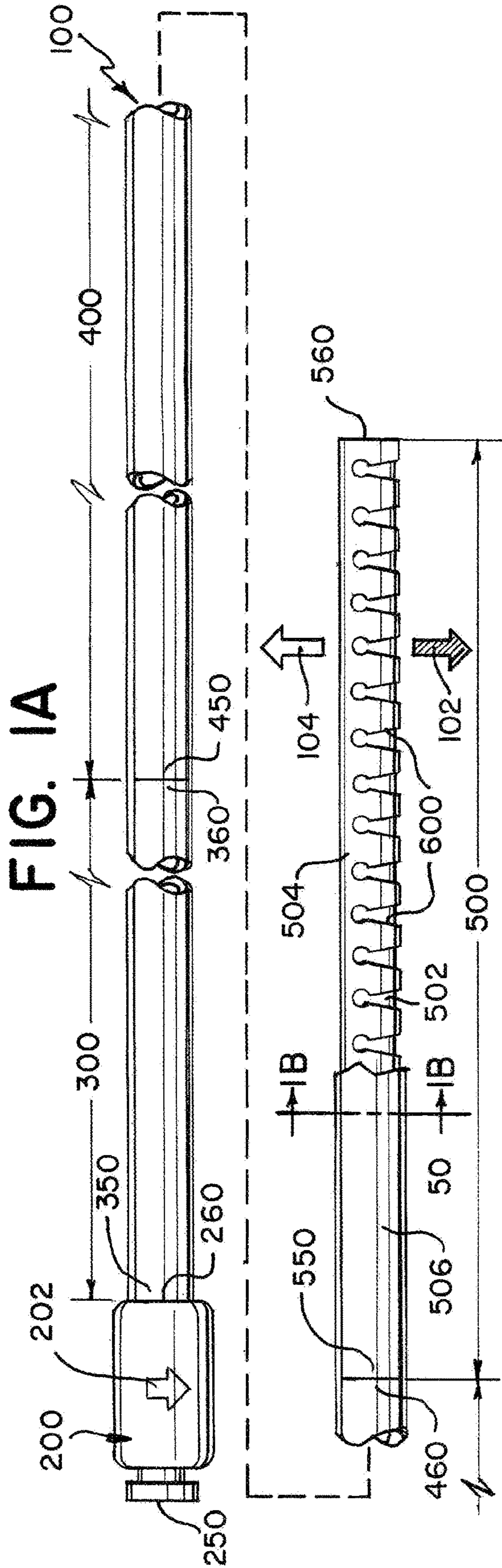
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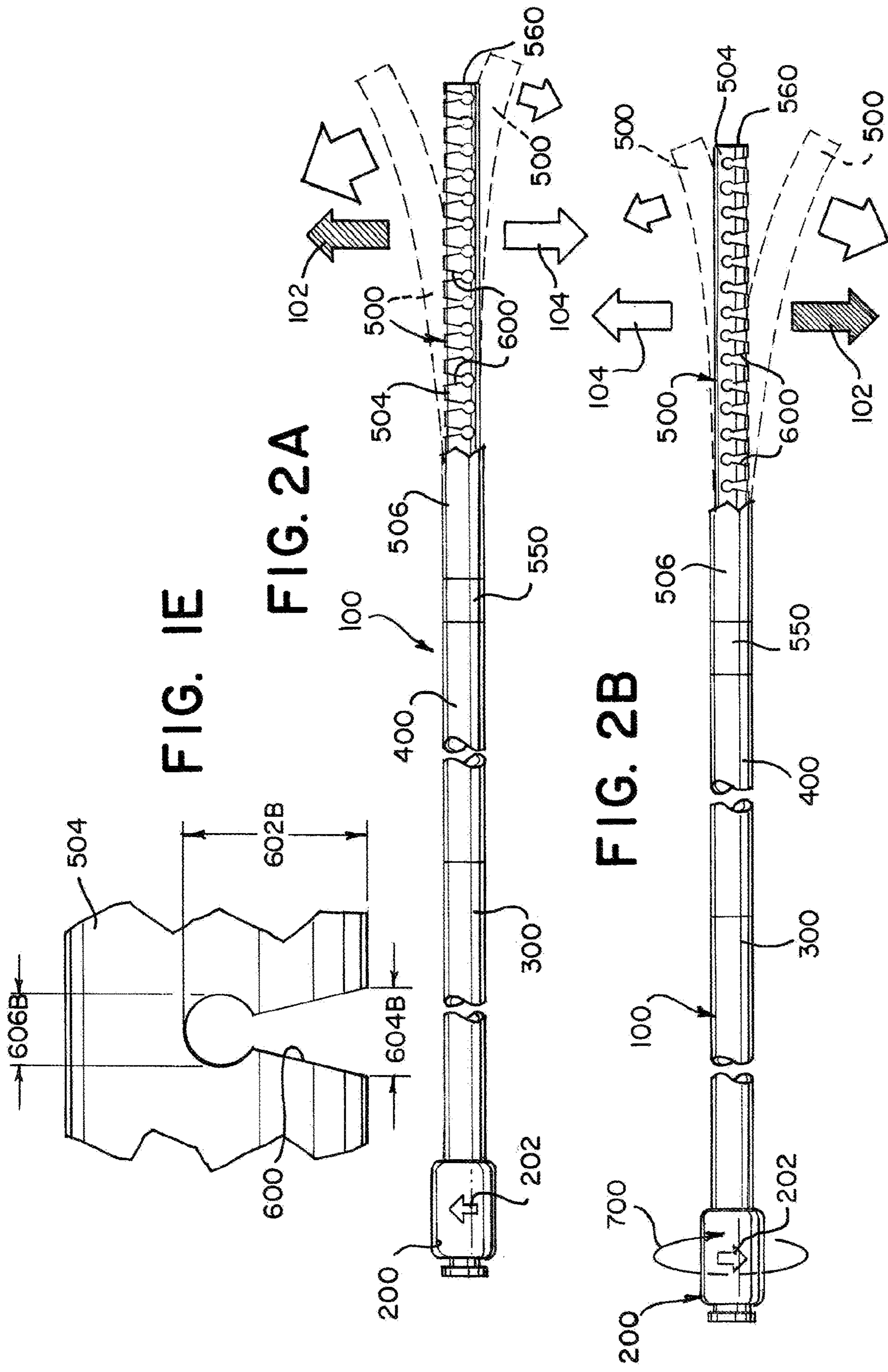


FIG. 1E

FIG. 2A

FIG. 2B

FIG. 2C

FIG. 3

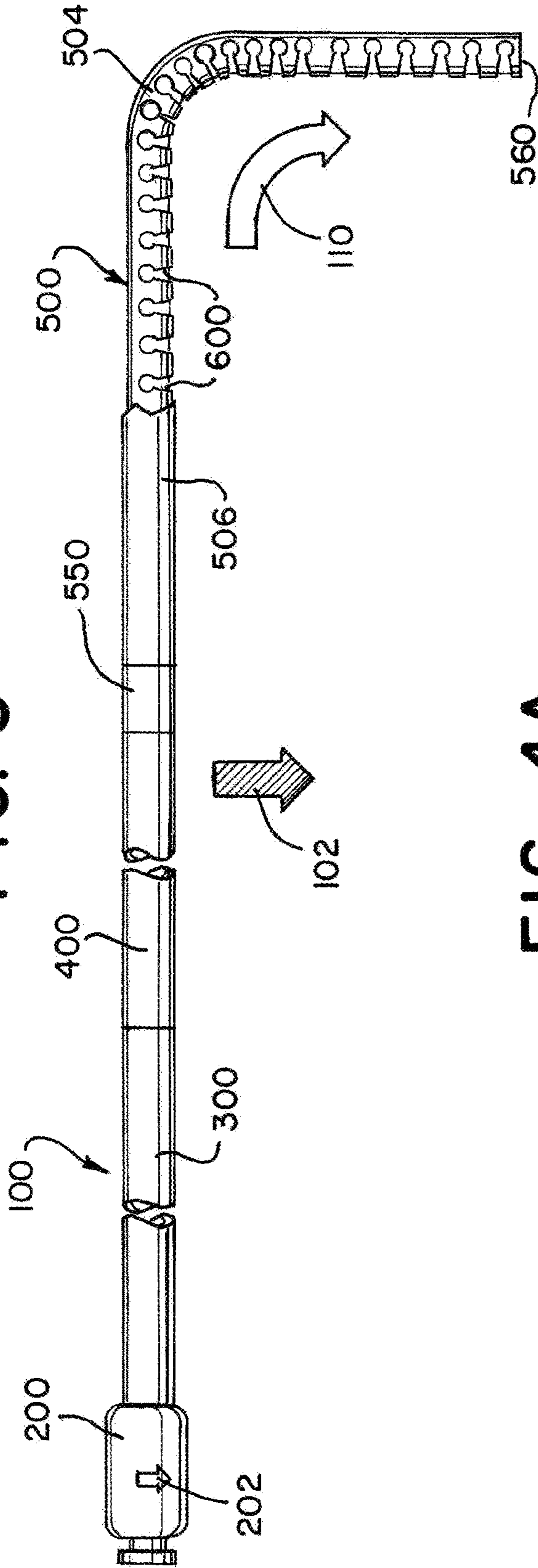
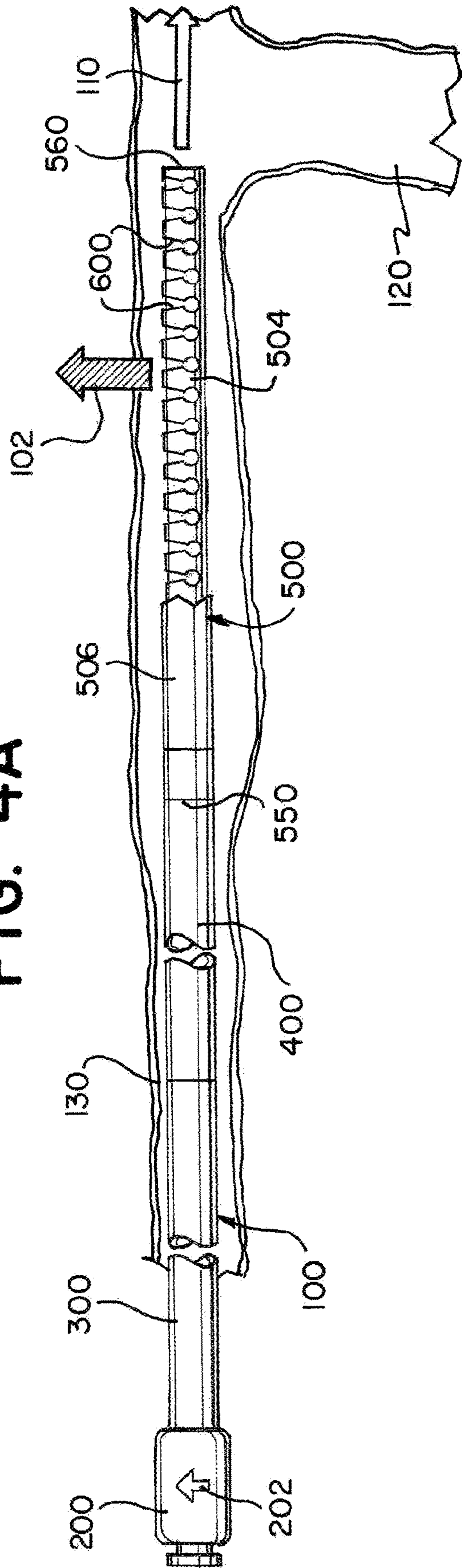


FIG. 4A



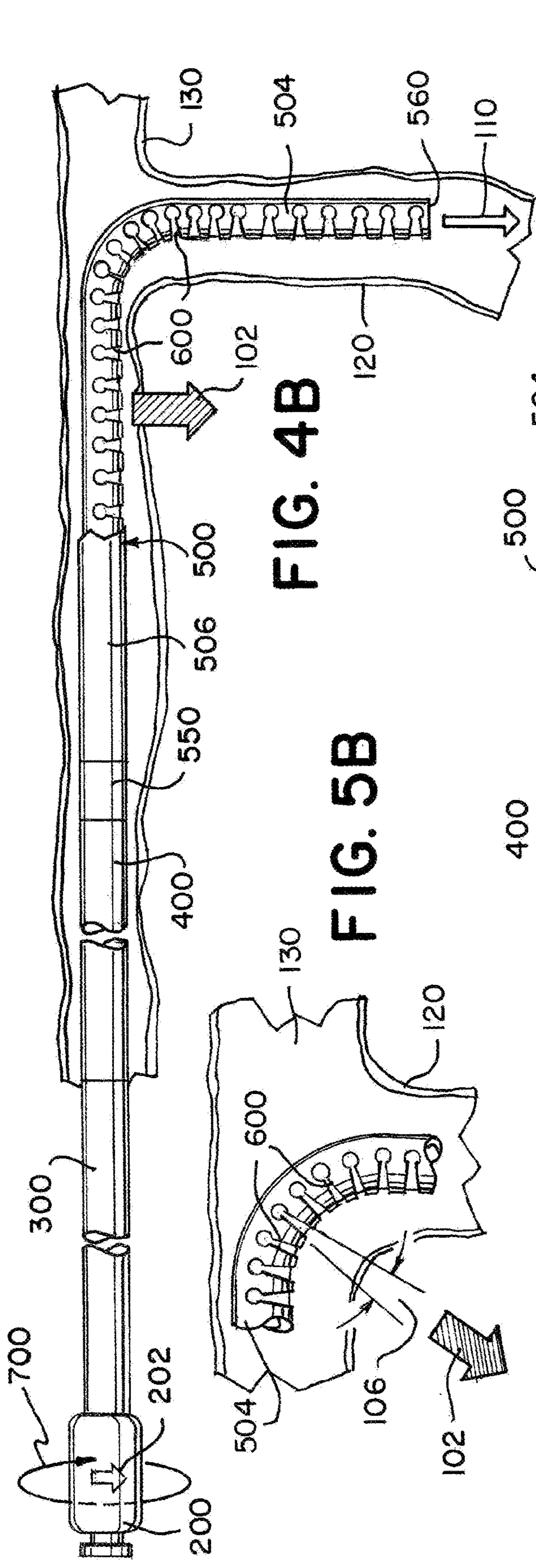


FIG. 4B

FIG. 5B

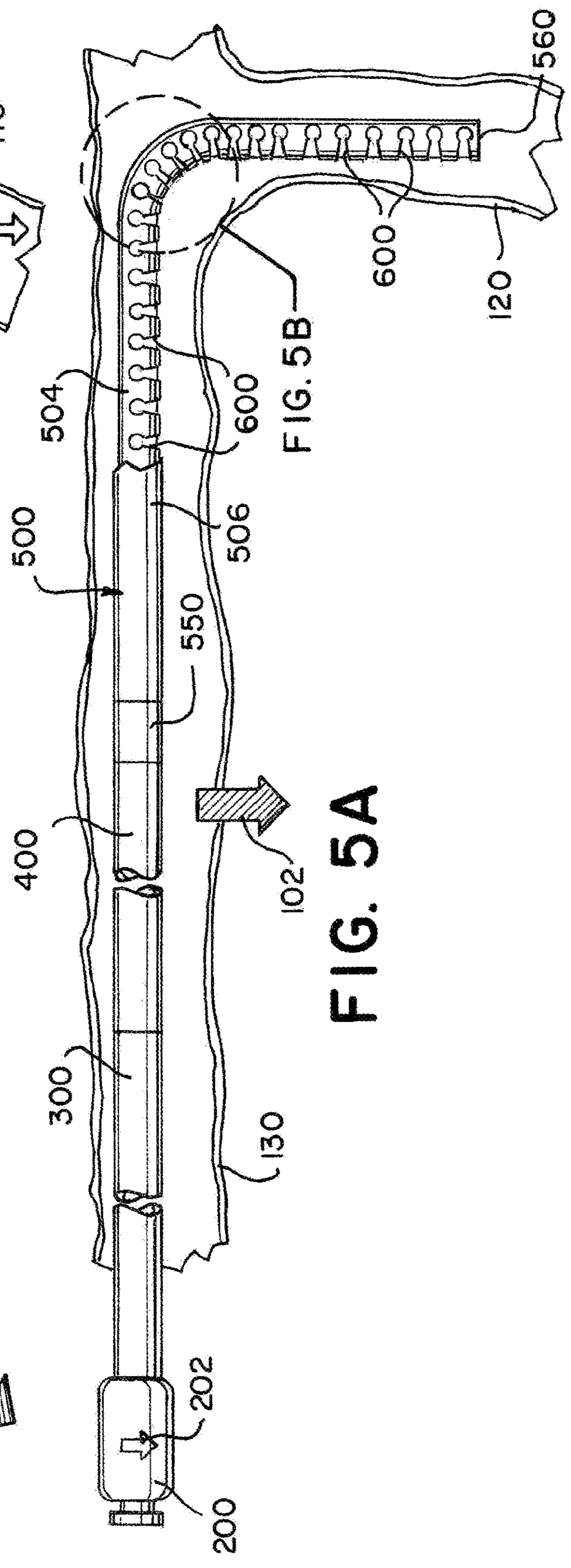


FIG. 5A

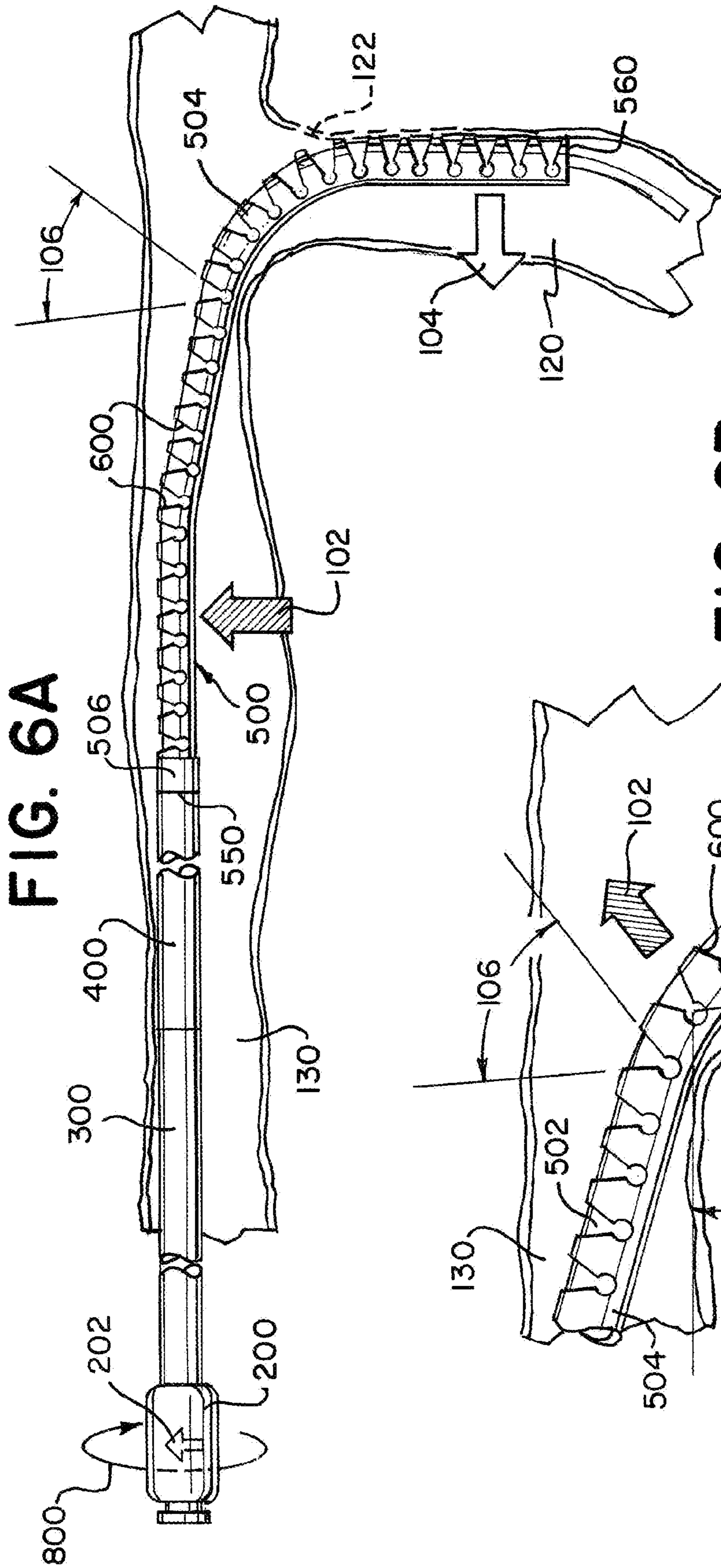


FIG. 6A

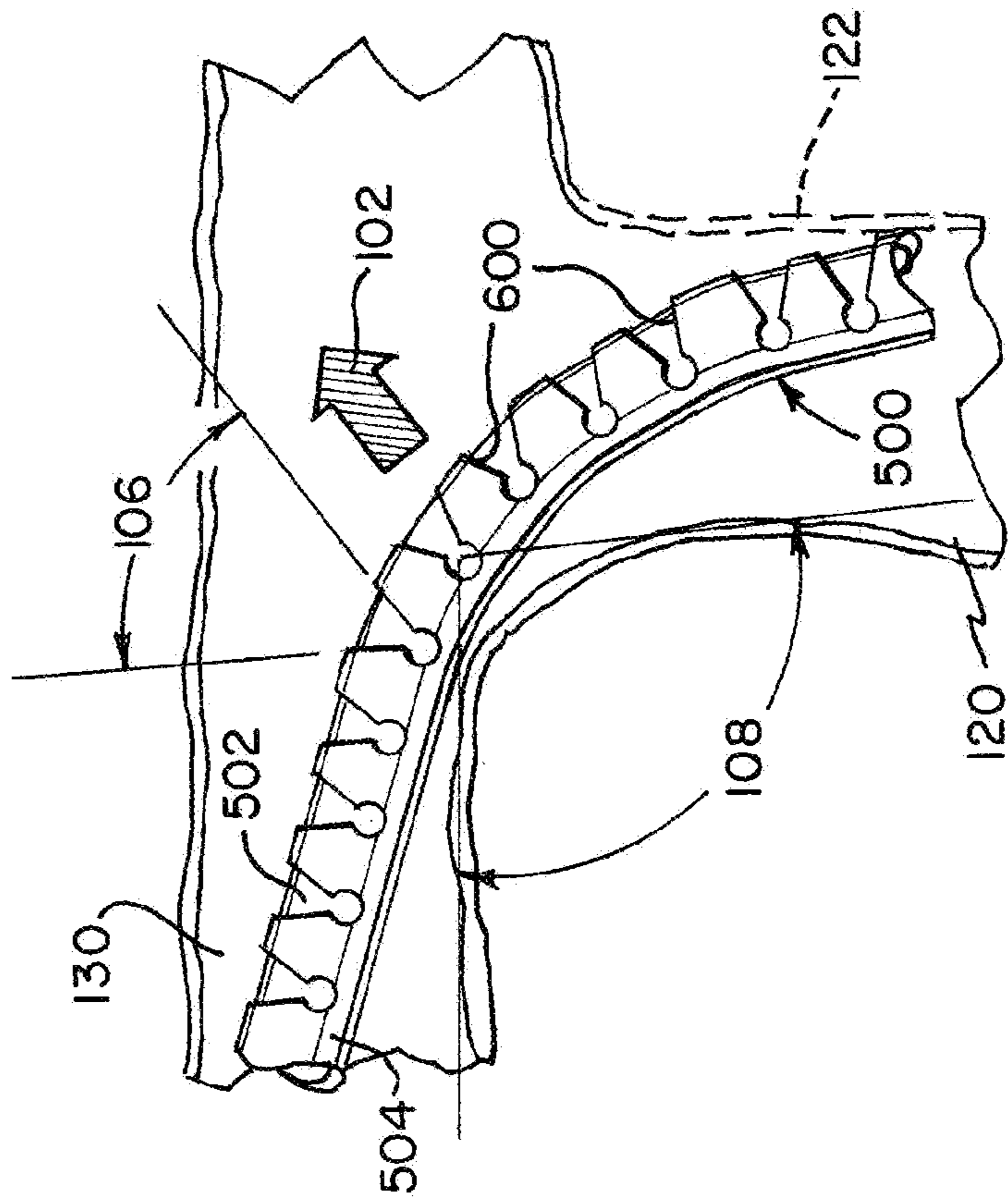


FIG. 6B

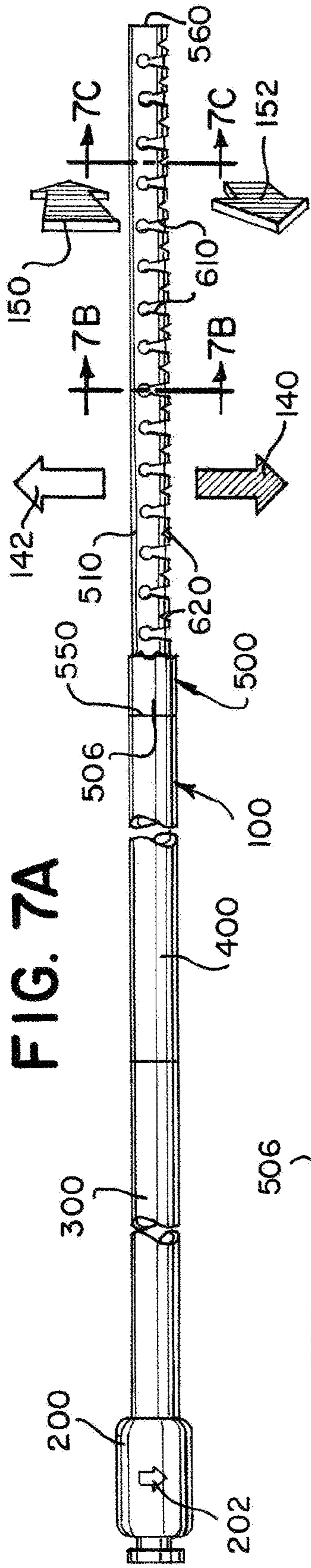


FIG. 7A

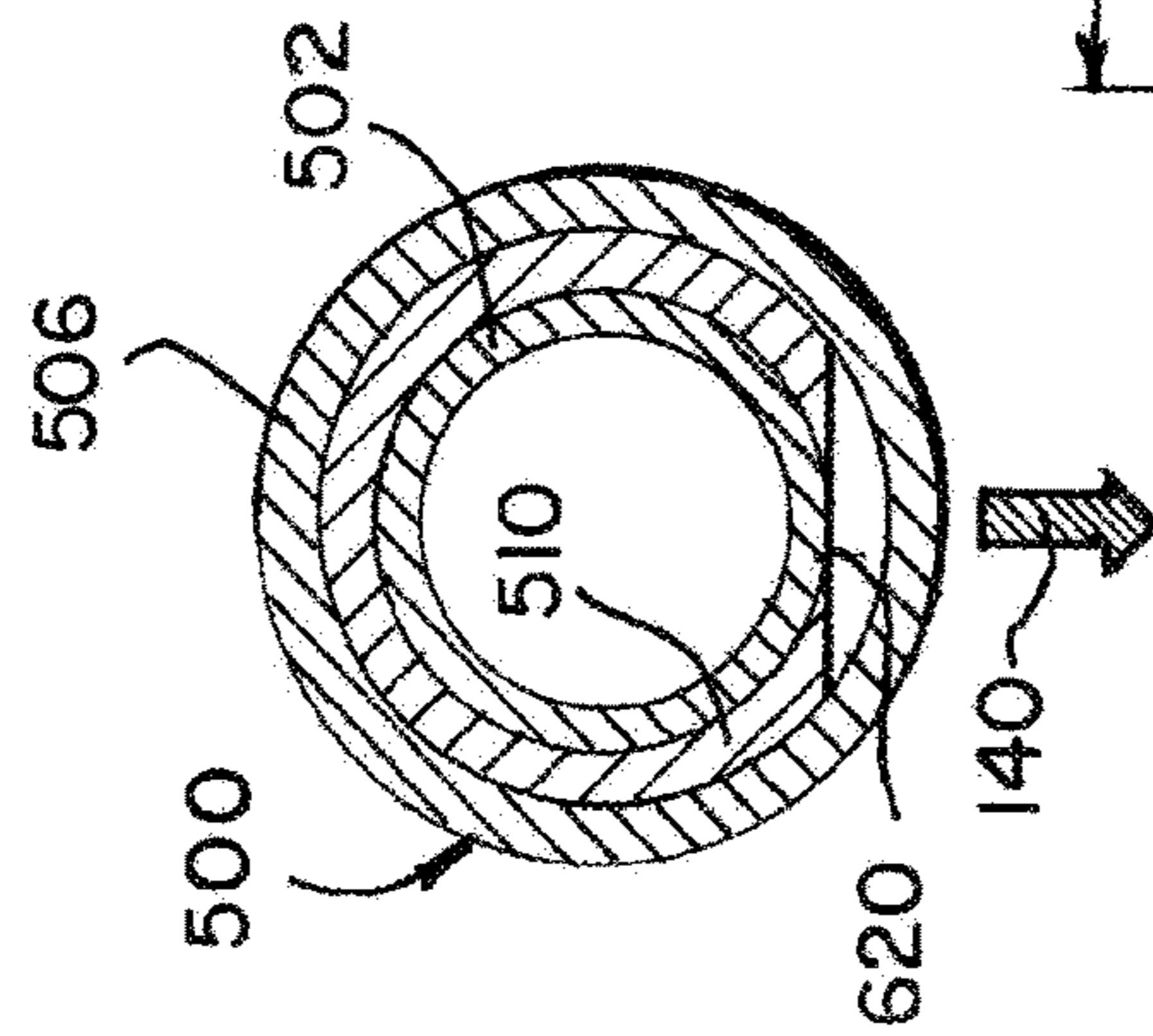


FIG. 7C

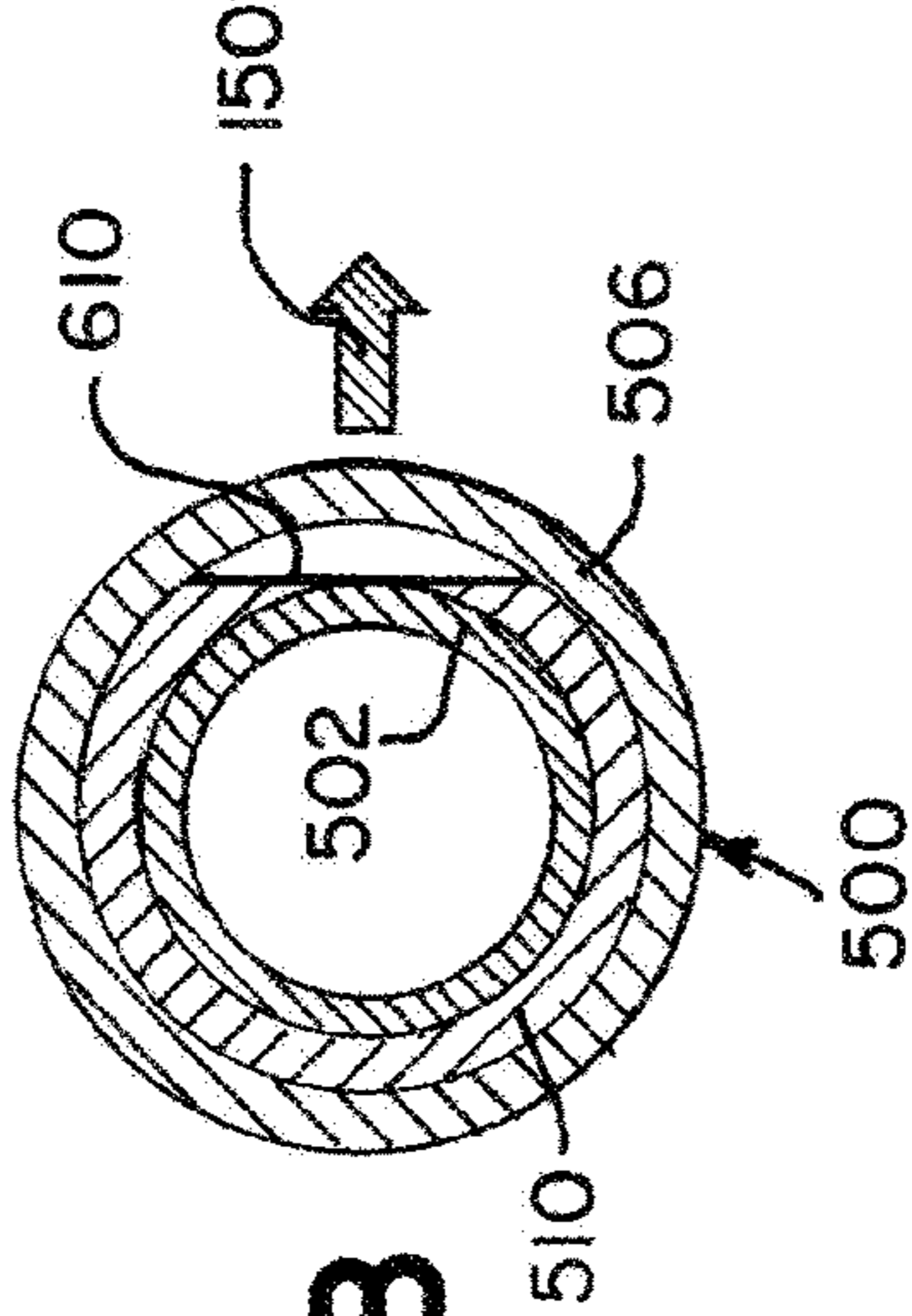


FIG. 7B

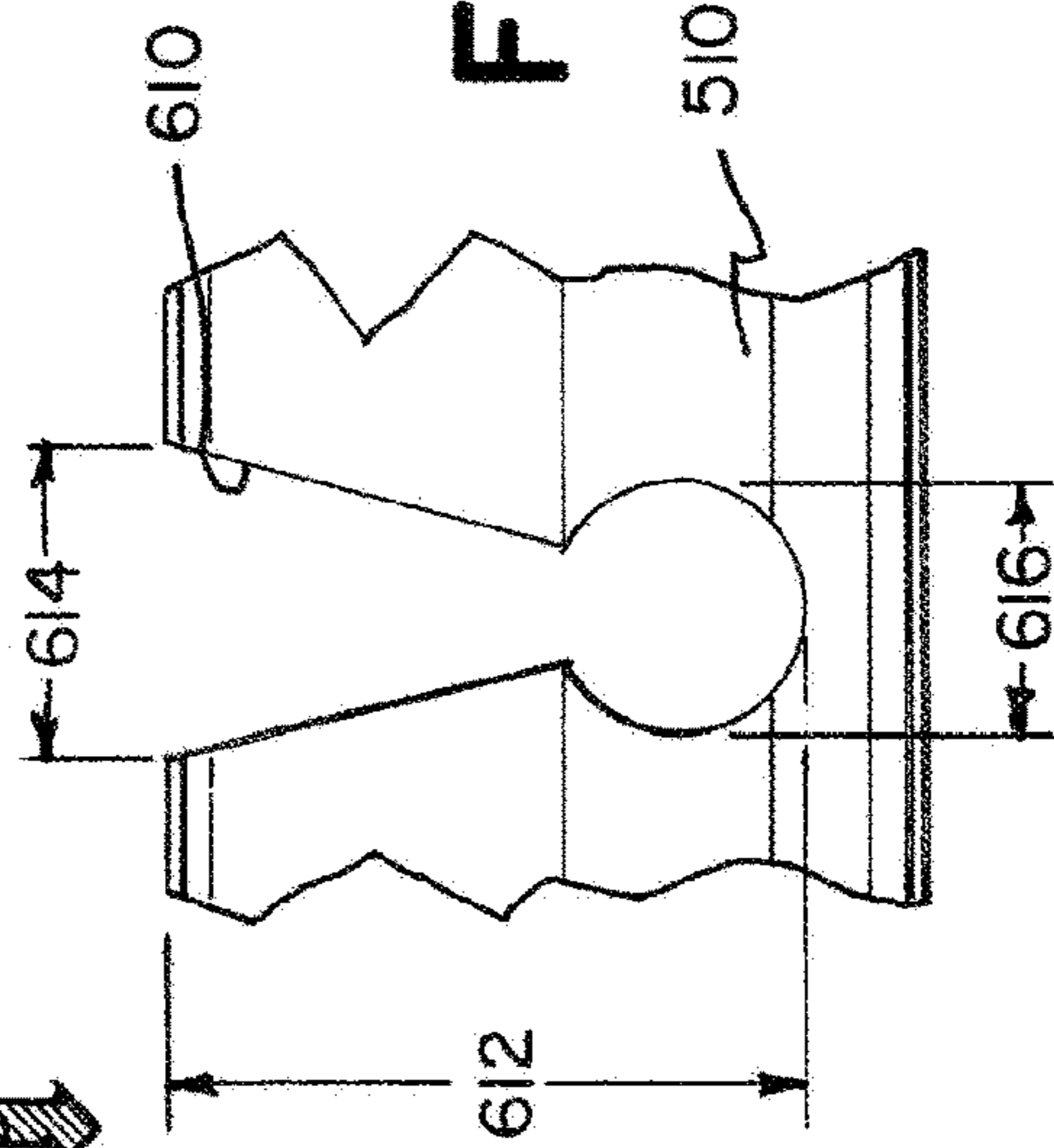


FIG. 7D

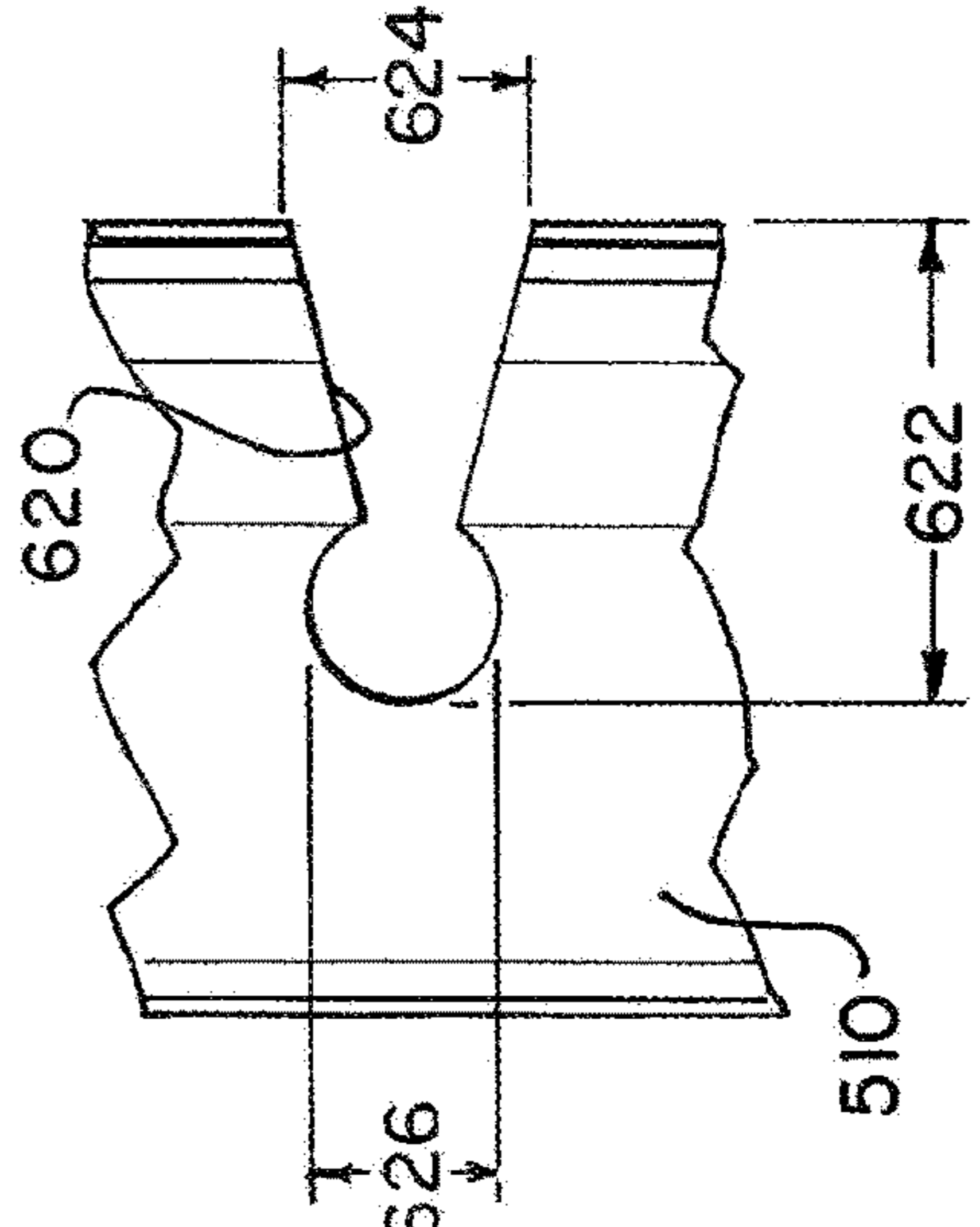


FIG. 7E



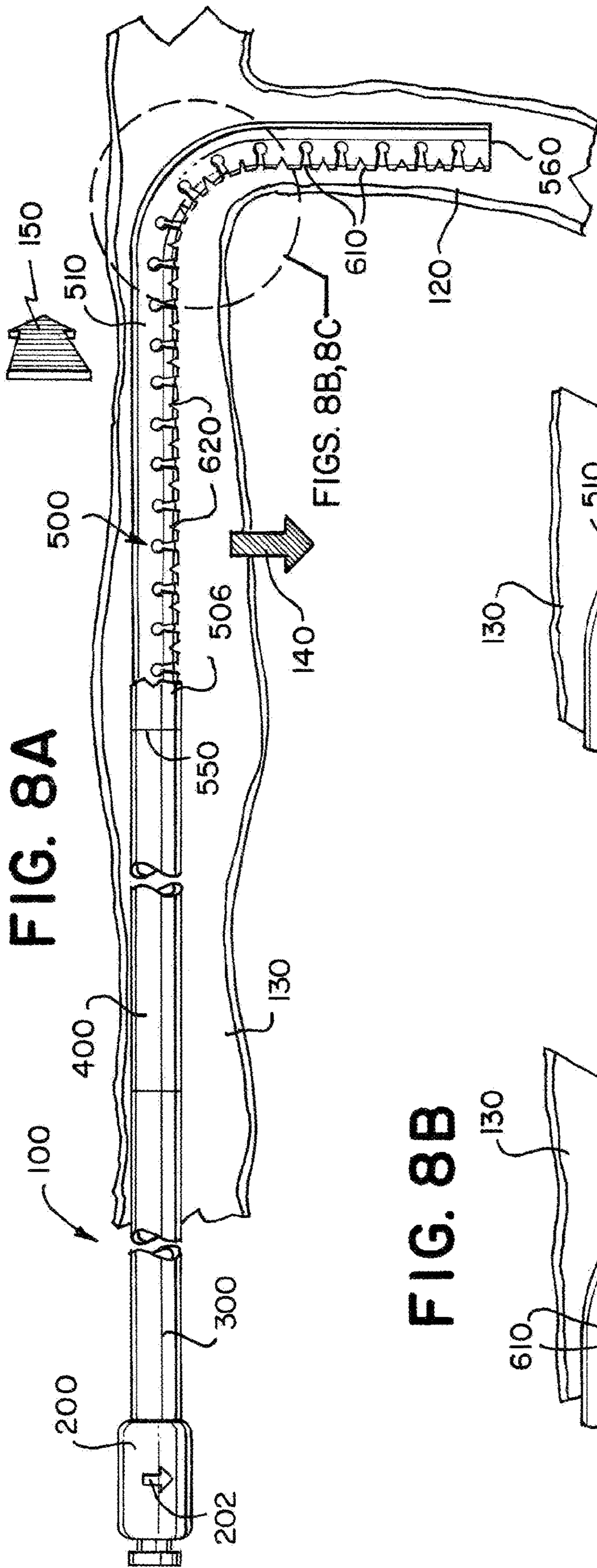


FIG. 8A

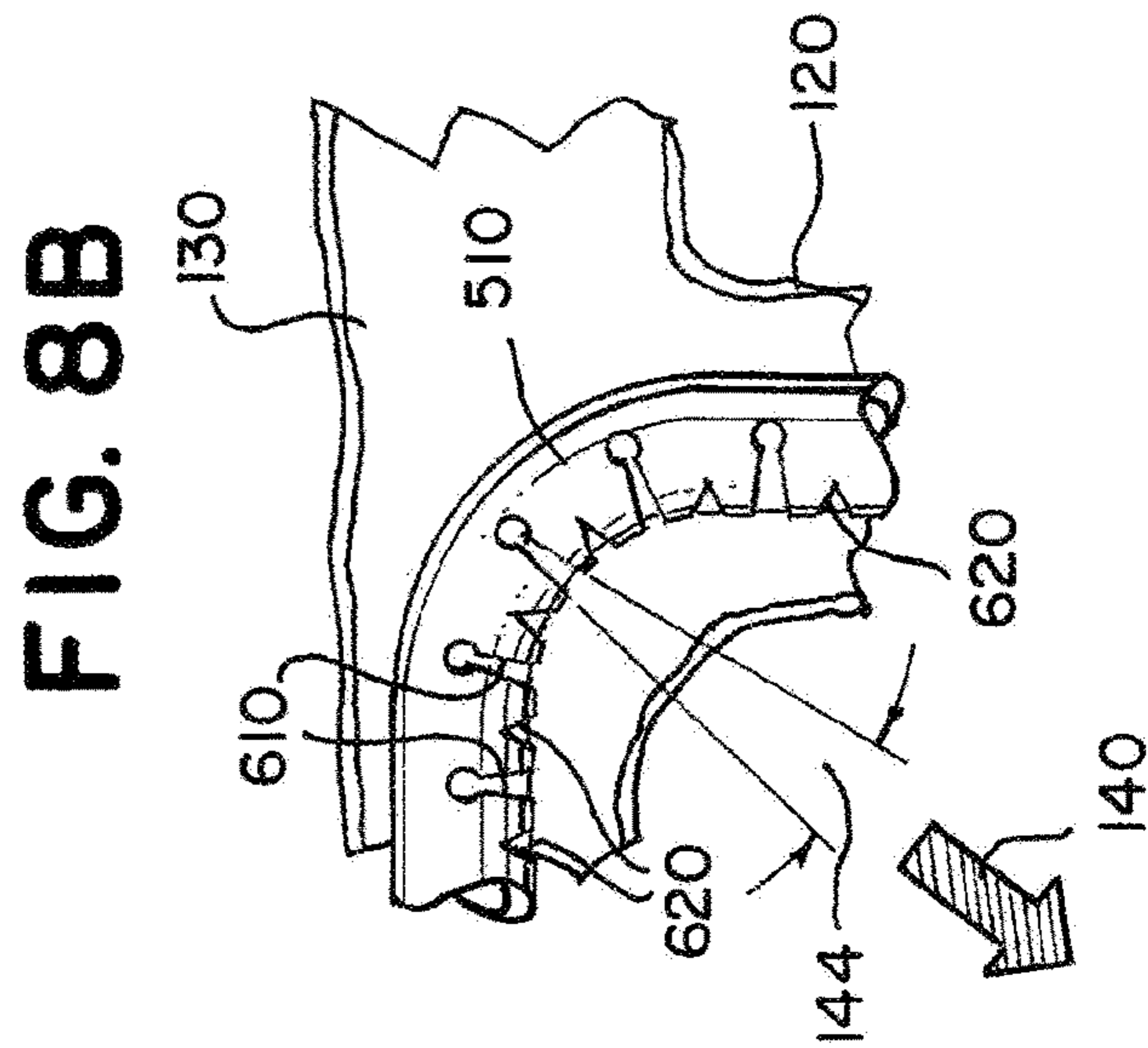


FIG. 8B

FIGS. 8B, 8C

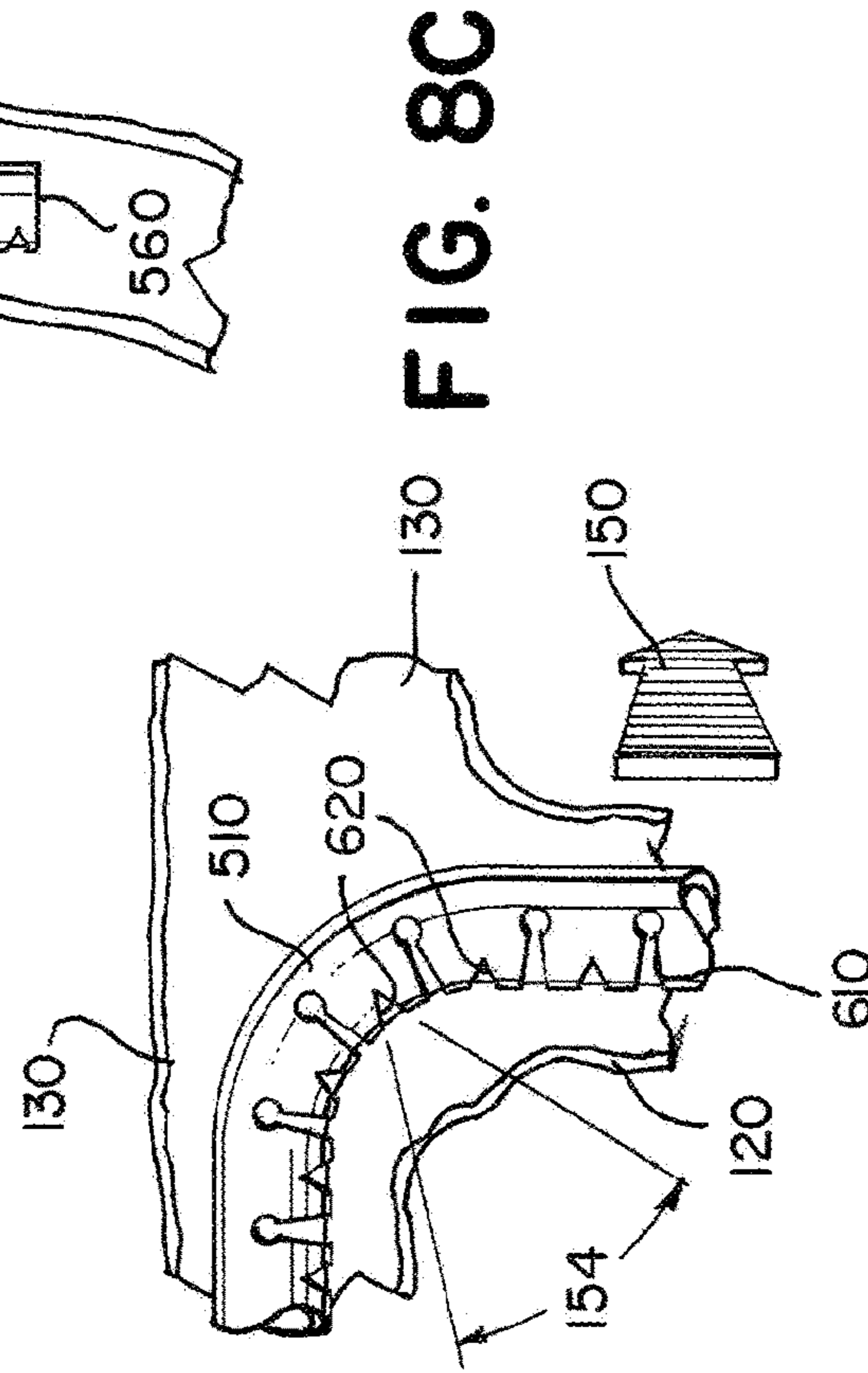


FIG. 8C

FIG. 9

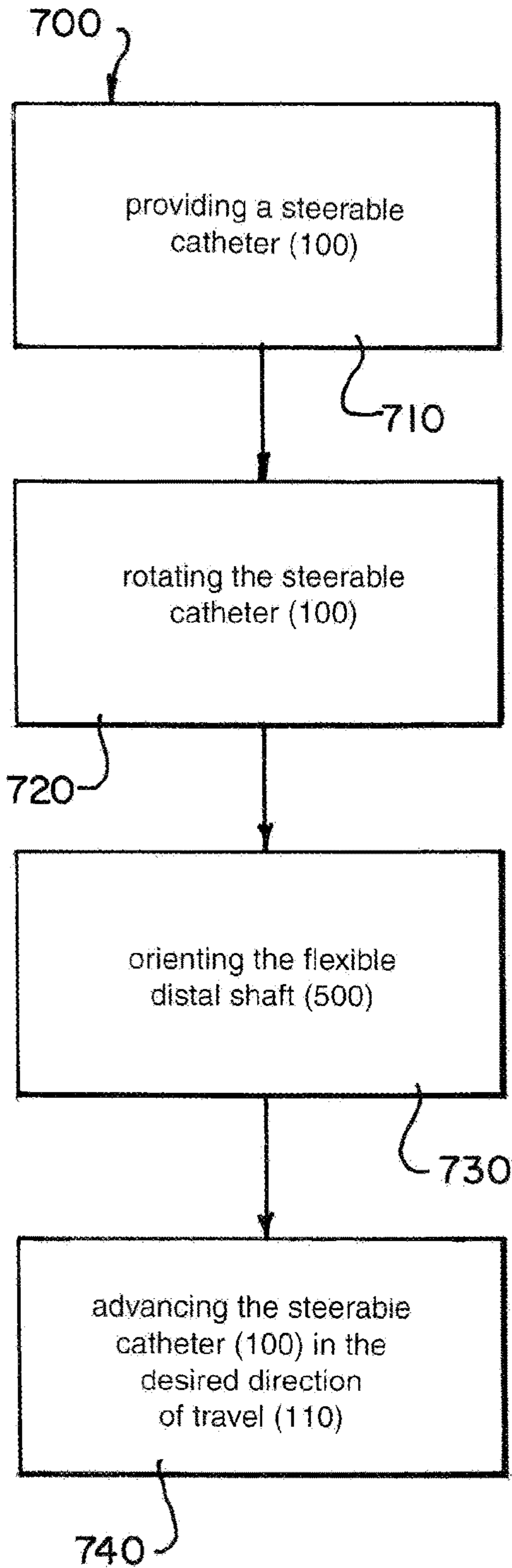
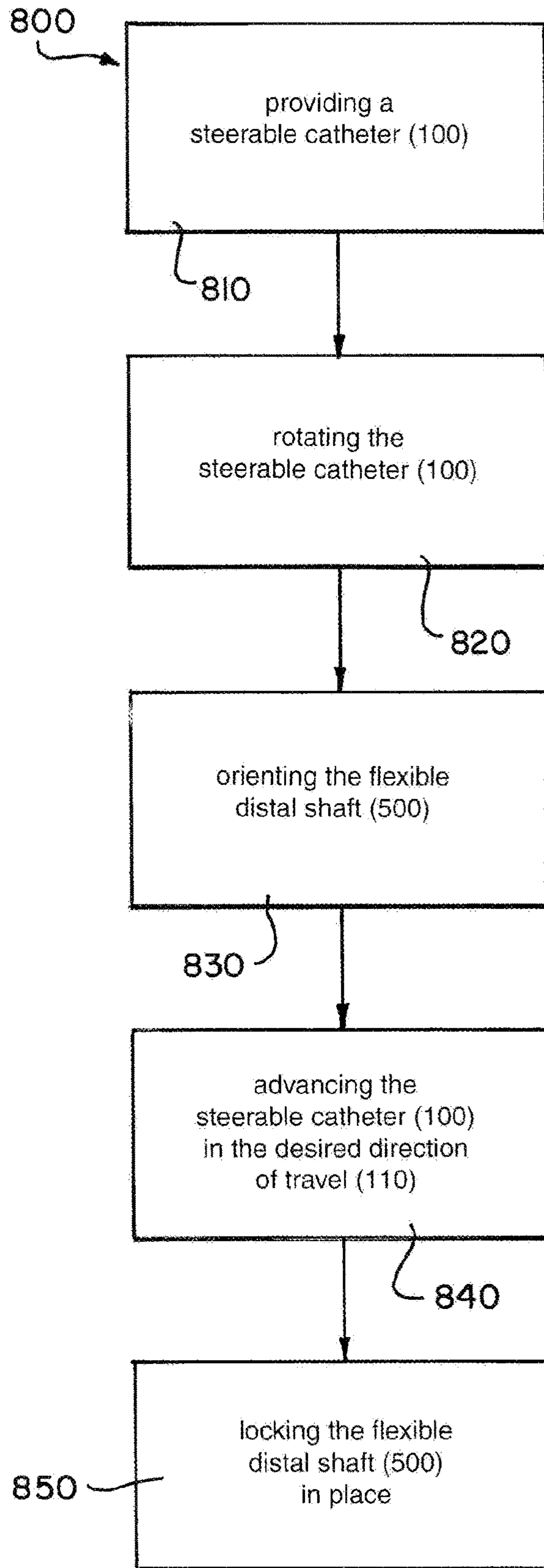


FIG. 10



**STEERABLE LOCKING CATHETER**PRIORITY AND CROSS-REFERENCE TO  
RELATED APPLICATION

This application is a continuation application under 35 USC§ 120 of U.S. non-provisional patent application Ser. No. 16/235,410, filed Dec. 28, 2018, now allowed, the contents of which are incorporated herein by reference in their entirety as if set forth verbatim.

## FIELD OF INVENTION

The present invention generally relates to medical instruments, and more particularly, to a steerable locking catheter system.

## BACKGROUND

Catheters can be pliable tubular structures that enter vasculature of a patient. Catheters can be used for a variety of purposes and applications. For example, they can be introduced into a particular area of interest within a vasculature and then act as a guide for introducing other peripheral, central venous, or arterial devices therein through its lumen. Such devices can include single or multi-lumen catheters, clot capturing devices, balloon catheters, and the like.

Tracking of catheters through tortuous anatomy can be challenging, especially for larger diameter catheters. These catheters are difficult to track in the presence of tortuosity and selecting branch vessels makes it more difficult. In addition, once the catheter is tracked through tortuous vasculature, and an interventional device (such as a stent, clot retriever, aspiration catheter, etc.) is advanced through the lumen of the catheter, it often results in the catheter backing out of position. If this occurs, the physician must remove the interventional device and then re-access the tortuous segment with the catheter prior to re-attempting delivery of the interventional device.

Therefore, there remains a need for new devices to safely and effectively advance catheters to locations of interest in a more controlled manner to resolve these and other problems of the art.

## SUMMARY

This invention facilitates the tracking and selection of branch vessels, as well as provide the means for stiffening the catheter body across the tortuosity to anchor the catheter and minimize the potential for the catheter backing out of position while delivering interventional devices to the distal anatomy.

The catheter consists of a torqueable shaft with a flexible distal end. The flexible distal end can be configured to be flexible in one direction and stiffer in the opposite direction. The flexibility of the distal end governed by a feature in the distal assembly designed to facilitate bending in one direction, while resisting bending in the opposite direction. The feature comprising a laser cut tubular element configured to flex preferentially in one direction while opposing flexure in the opposite direction. The tubular element is encapsulated (fused) between layers of flexible polymer.

The hub of the catheter is labeled to indicate the direction of flexibility so that the user can more easily steer the catheter through the vasculature. If the user approaches a bifurcation and desires to track down the vessel rather than

in the direction of the bifurcated vessel, the user torques the shaft such that the flexible direction of the distal element is away from the bifurcation, thus facilitating tracking of the device away from the bifurcation. If the user desires to track in the direction of the bifurcation, the user will then torque the shaft such that the flexible direction of the distal element is in the direction of the bifurcation, thus facilitating access to the bifurcated vessel. To access through tortuosity and prevent the catheter from backing out of position, the user first aligns the flexible segment to access through tortuosity as described above. Once the catheter has crossed the tortuous segment, the user torques the catheter such that the flexible segment reverts inside of the dominant curve and the less flexible segment stiffens inside the curve. This results in the catheter locking itself in the curve and resisting backwards movement as interventional devices are tracked through its lumen.

Disclosed herein are various exemplary devices for a steerable catheter or steerable locking catheter that can address tracking of catheter through tortuous anatomy and other problems of the art.

The devices can generally include a proximal hub, a proximal shaft, an intermediate shaft, and a flexible distal shaft. The flexible distal shaft having a proximal end and a distal end. The intermediate shaft having a proximal end and a distal end wherein the distal end of the intermediate shaft is connected to the proximal end of the flexible distal shaft. The proximal shaft having a proximal end and a distal end, wherein the distal end of the proximal shaft is connected to the proximal end of the intermediate shaft. The proximal hub comprising a proximal end and a distal end, wherein the distal end of the proximal hub is connected to the proximal end of the proximal shaft.

The devices can also generally include a flexible distal shaft that has a first direction of flexibility and a second direction of flexibility opposite to the first direction of flexibility. The flexible distal shaft can be torqued such that the first direction of flexibility is in the direction of the desired direction of travel, thus facilitating access to the bifurcation of the vasculature or a desired vessel. The devices can also generally include three layers, an inner layer, a segmented mid-layer with a plurality of notches, and an outer layer. The segmented mid-layer's notches have a depth and an outer depth and an inner width which relates to the angle of flexibility and enables the flexible distal shaft to bend in the first direction of flexibility.

An example device for a steerable catheter can include notches wherein the outer width is greater than the inner width. The greater outer width enables the flexible distal shaft to have greater flexibility in the first direction of flexibility. Another example device for a steerable catheter can include notches that are different depths and widths. The first depth and second depth of the notches can be selected to provide increased, decreased, or the same flexibility as notches having the same depth. The first depth and second depth can be selected to provide customization to the flexibility enabling increased or decreased flexibility at a specific point or points or location or locations on the flexible distal shaft. The first outer width and second outer width can be selected to provide increased, decreased, or the same flexibility as notches having the same outer width. The first outer width and second outer width depth can be selected to provide customization to the flexibility enabling increased or decreased flexibility at a specific point or points or location or locations on the flexible distal shaft.

The first inner width and second inner width can be selected to provide increased, decreased, or the same flex-

ibility as notches having the same inner width. The first inner width and second inner width depth can be selected to provide customization to the flexibility enabling increased or decreased flexibility at a specific point or points or location or locations on the flexible distal shaft.

Another example device for a steerable catheter can include notches of a first geometric shape. The notch's geometric shape can be selected to provide a variety of flexibility including increased flexibility or decreased flexibility. The notch's geometric shape can be selected to provide customization to the flexibility enabling increased or decreased flexibility at a specific point or points or location or locations on the flexible distal shaft.

Another example for a steerable catheter can include notches of two geometric shapes wherein there is at least one notch with a first geometric shape and at least one notch with a second geometric shape.

The two geometric shapes can be selected to provide a variety of flexibility including increased or decreased flexibility. The two geometric shapes can be selected to provide customization to the flexibility enabling increased or decreased flexibility at a specific point or points or location or locations on the flexible distal shaft.

Another example a steerable catheter can include a notch or notches in a number of different orientations. The different orientations of the notches can be selected to provide a variety of flexibility including increased or decreased flexibility. The different orientations of the notches can be selected to provide customization to the flexibility enabling increased or decreased flexibility at a specific point or points or location or locations on the flexible distal shaft.

Another example for a steerable catheter can include a segmented mid-layer. The segmented mid-layer can have notches. The notches have a depth and an outer and an inner width that relate to the first angle of flexibility and enables the flexible distal shaft to bend in the first direction of flexibility. Additionally, the notches have a depth and an outer and an inner width that relate to the second angle of flexibility that is opposite that of the first angle of flexibility. The segmented mid-layer and notches can be configured to resist bending the second direction of flexibility.

Another example for a steerable catheter can include an outer layer. The outer layer can be made from a variety of materials suitable for a catheter including an elastic material. The outer layer can also include a radiopaque element to facilitate the identification of the first direction of flexibility. The outer layer can also include a radiopaque element to facilitate the identification of the second direction of flexibility. The outer layer can also include a radiopaque element to facilitate the identification of the first direction of flexibility.

Another example for a steerable catheter can include the proximal shaft having a proximal shaft flexibility and the intermediate shaft having an intermediate shaft flexibility. The flexibility of the flexible distal shaft can be greater than, less than, or equal to the intermediate shaft flexibility. The flexibility of the flexible distal shaft can be greater than, less than, or equal to the proximal shaft flexibility. The flexibility of the intermediate shaft can be greater than, less than, or equal to the proximal shaft flexibility. Additionally, the flexibility of the proximal shaft can be greater than, less than, or equal to the proximal shaft flexibility.

Another example for a steerable catheter can include the proximal hub having a label to indicate the first direction of flexibility of the steerable catheter. The proximal hub can also have a label to indicate the second direction of flexibility of the steerable catheter.

An example method of steering a steerable catheter can include a flexible distal shaft with a first direction of flexibility, a segmented mid-layer with a plurality of notches having a depth, an outer width, and an inner width, rotating the steerable catheter, orienting the flexible distal shaft such that the first direction of flexibility facilitates travel in a desired direction of travel, advancing the steerable catheter in the desired direction of travel.

The method can include notches where the outer width is greater than the inner width. The method can include notches where the plurality of notches is configured to bend in the first direction of flexibility. The method can include a flexible distal shaft with a second direction of flexibility. The method can include a flexible distal shaft with a second direction of flexibility opposite to the first direction of flexibility. The method can include a flexible distal shaft where the flexibility of the flexible distal shaft is greater in the first direction of flexibility than any other direction.

An example method of locking a steerable catheter can include a flexible distal shaft with a first direction of flexibility, a segmented mid-layer with a plurality of notches having a depth, an outer width, and an inner width, rotating the steerable catheter, orienting the flexible distal shaft such that the first direction of flexibility facilitates travel in a desired direction of travel, advancing the steerable catheter in the desired direction of travel.

The method of locking a steerable catheter can include notches where the outer width is greater than the inner width. The method can include notches where the plurality of notches is configured to bend in the first direction of flexibility. The method can include a flexible distal shaft with a second direction of flexibility. The method can include a flexible distal shaft with a second direction of flexibility opposite to the first direction of flexibility. The method can include a flexible distal shaft where the flexibility of the flexible distal shaft is greater in the first direction of flexibility than any other direction.

The method of locking a steerable catheter can include locking the flexible distal shaft in place by rotating the steerable catheter to orient the first direction of flexibility such that the flexible distal shaft contacts a wall of vessel branch to limit movement of the flexible distal shaft in the desired direction of travel.

The method of locking a steerable catheter can include locking the flexible distal shaft in place by rotating the steerable catheter to orient the first direction of flexibility and second direction of flexibility such that the flexible distal shaft contacts a wall of vessel branch to limit movement of the flexible distal shaft in the desired direction of travel.

An example of a steerable catheter can include different orientations of notches to provide for a first primary direction of flexibility, a second primary direction of flexibility, a first secondary direction of flexibility, and a second secondary direction of flexibility. Where the first primary direction of flexibility is not in the same direction of the second primary direction of flexibility. Where the first secondary direction of flexibility is not the same direction of the second secondary direction of flexibility.

The example can include an inner layer, a segmented mid-layer with different oriented notches, and an outer layer. The example can include a segmented mid-layer with a primary plurality of notches with a primary depth, a primary outer width, and a primary inner width. The example can include a segmented mid-layer where the primary depth, the primary outer width, and the primary inner width are related to the primary angle of flexibility. The example can include

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a segmented mid-layer where the primary outer width is greater than the primary inner width. The example can include a segmented mid-layer where the primary plurality of notches is configured to bend in the first primary direction of flexibility.

The example can include a secondary plurality of notches with a secondary depth, a secondary outer width, and a secondary inner width. The example can include a secondary plurality of notches where the secondary depth, the secondary outer width, and the secondary inner width are related to the secondary angle of flexibility. The example can include a secondary plurality of notches where the secondary outer width is greater than the secondary inner width. The example can include a secondary plurality of notches where the secondary plurality of notches is configured to bend in the first secondary direction of flexibility.

Another example of the steerable catheter can include a label to indicate the first primary direction of flexibility. The example can include a label to indicate the first secondary direction of flexibility. Another example for a steerable catheter can include an outer layer. The outer layer can be made from a variety of materials suitable for a catheter including an elastic material. The outer layer can also include a radiopaque element to facilitate the identification of the first primary direction of flexibility. The outer layer can also include a radiopaque element to facilitate the identification of the second primary direction of flexibility. The outer layer can also include a radiopaque element to facilitate the identification of the first secondary direction of flexibility. The outer layer can also include a radiopaque element to facilitate the identification of the second secondary direction of flexibility.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The above and further aspects of this invention are further discussed with reference to the

following description in conjunction with the accompanying drawings, in which like numerals indicate like structural elements and features in various figures. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating principles of the invention. The figures depict one or more implementations of the inventive devices, by way of example only, not by way of limitation.

FIG. 1A is a side view illustration of the steerable locking catheter of the present invention.

FIG. 1B is a cross-sectional view illustration of the notches located at the distal end of the present invention shown in FIG. 1A.

FIGS. 1C to 1E are illustrations of the notches of the present invention.

FIGS. 2A to 2B are side view illustrations of the directions of flexibility of the present invention.

FIG. 3 is a side view illustration of the flexible distal shaft flexed in the first direction of flexibility.

FIGS. 4A to 4B are side view illustrations of the method of steering a steerable catheter to orient the first direction of flexibility in the desired direction of travel.

FIGS. 5A to 5B are side view illustrations of the steerable catheter located within the desired vessel branch and the orientation of the first direction of flexibility.

FIGS. 6A to 6B are side view illustrations of the method of locking a steerable catheter to orient the first direction of flexibility such that the flexible distal shaft contacts a wall of the vessel branch to limit movement of the flexible distal shaft.

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FIG. 7A is a side view illustration of the steerable locking catheter with notches having two different orientations of the present invention.

FIGS. 7B to 7E are side view illustrations of the notches with different orientations located at the distal end of the present invention shown in FIG. 7A.

FIGS. 8A to 8C are side view illustrations of the steerable catheter with notches with different orientations located within the desired vessel branch.

FIG. 9 is an illustration of an exemplary steering sequence of the exemplary device according to aspects of the present invention.

FIG. 10 is an illustration of an exemplary locking sequence of the exemplary device according to aspects of the present invention.

#### DETAILED DESCRIPTION

FIG. 1A illustrates a side view of the steerable catheter. As illustrated, the steerable catheter **100** can have a proximal hub **200**, a proximal shaft **300**, an intermediate shaft **400**, and a flexible distal shaft. The proximal hub **200** can have a proximal end **250** and a distal end **260**. The proximal hub **200** can have a label **202**. The proximal shaft **300** can have a proximal end **350** and a distal end **360**. The intermediate shaft **400** can have a proximal end **450** and a distal end **460**. The flexible distal shaft can have a proximal end **550** and a distal end **560**. The distal end **260** of the proximal hub **200** can be connected to the proximal end **350** of the proximal shaft **300**. The distal end **360** of the proximal shaft **300** can be connected to the proximal end **450** of the intermediate shaft **400**. The distal end **460** of the intermediate shaft **400** can be connected to the proximal end **550** of the flexible distal shaft. The steerable catheter **100** can have a first direction of flexibility **102**. The steerable catheter **100** can have a second direction of flexibility **104**. The first direction of flexibility **102** can be opposite to that of the second direction of flexibility **104**.

The proximal shaft **300** can have a proximal shaft flexibility and the intermediate shaft **400** can have an intermediate shaft flexibility. The flexibility of the intermediate shaft **400** can be greater than the proximal shaft flexibility and the flexibility of the flexible distal shaft **500** is greater than both the intermediate shaft and proximal shaft flexibility. This varying stiffness, or flexibility, along the length of the steerable catheter **100** allows for an easier transfer of torque from the proximal hub **200** to the flexible distal shaft **500**. This permits the user to apply torque to the proximal hub **200** to easily orientate the flexible distal shaft **500** in the needed radial direction to utilize either the first or second direction of flexibility **102**, **104** to advance the catheter through the vasculature. Note that certain catheters **100** can be advanced from a patient's inner thigh, over the cardiac arch, and up into the neurovascular inside the patient's skull and thus the distance and tortuosity can be significant.

The changes in flexibility between the proximal shaft and the intermediate shaft can be from using different materials for each portion of the shaft, each portion being of a different stiffness or durometer. Alternately, the proximal and intermediate shafts can be made of the same material and additional layers or additives can be provided in the shafts to control the individual stiffness. These examples can be combined to provide the needed flexibility and/or stiffness. Note that each of the proximal shaft **300** and the intermediate shaft **400** can have uniform stiffness across their length, or it can vary. As an example, the stiffness of the proximal shaft **300** can decrease from the proximal end **350**

to the distal end **360**, so the stiffness of the distal end **360** matches the stiffness of the proximal end **450** of the intermediate shaft **400**. This gradual transition of stiffness, in certain examples, can prevent localized stiffness “transition points”.

FIG. 1B illustrates a cross-section of the steerable catheter depicted in FIG. 1A. As illustrated, the steerable catheter **100** can have an inner layer **502**, a segmented mid-layer **504**, and an outer layer **506**. The segmented mid-layer **504** can have notches **600** as depicted in FIGS. 1C, 1D, and 1E. The segmented mid-layer **504** and the size and shape of the notches **600** can relate to the first direction of flexibility **102**. The segmented mid-layer **504** and the size and shape of the notches **600** can relate to the second direction of flexibility **104**. As with all catheters **100**, there is an inner lumen **108** passing along the inside the catheter **100** to permit the delivery of surgical tools or implements or provide passage for the removal of clots, tissue, or fluid from the patient.

FIGS. 1C, 1D, and 1E illustrate the variety of notches. The notch **600** is located within the segmented mid-layer **504**. The notch **600** can have a depth **602**, **602A**, or **602B**. The notch can have an outer width **604**, **604A**, or **604B**. The notch can have an inner width **606**, **606A**, or **606B**. FIG. 1C depicts a uniformly sized notch **600** wherein the plurality of notches can have the same depth **602**, outer width **604**, and inner width **606**. FIGS. 1D and 1E depict two different sized notches wherein the first depth **602A** can be different than the second depth **602B**. The first outer width **604A** can be different than the second outer width **604B**. The first inner width **606A** can be different than the second inner width **606B**.

The depth **602**, outer width **604**, and inner width **606** can relate to the flexibility in the first direction of flexibility **102**. The depth **602**, outer width **604**, and inner width **606** can relate to the flexibility in the second direction of flexibility **104**. The first depth **602A**, first outer width **604A**, and first inner width **606A** can relate to the flexibility in the first direction of flexibility **102**. The first depth **602A**, first outer width **604A**, and first inner width **606A** can relate to the flexibility in the second direction of flexibility **104**. The second depth **602B**, second outer width **604B**, and second inner width **606B** can relate to the flexibility in the first direction of flexibility **102**. The second depth **602B**, second outer width **604B**, and second inner width **606B** can relate to the flexibility in the second direction of flexibility **104**.

In examples, the first direction of flexibility **102** of the steerable catheter **100** can provide more flexibility than the second direction of flexibility **104**. In one example, the first direction of flexibility **102** can be provided by closing the notch **600** while the second direction of flexibility **104** can be provided by opening the notch **600**. The closing of the notch **600** can be provided by causing the sides defined by the outer width (**604**, **604A**, or **604B**) of the notch **600** to touch or at least be closer to one another than when not flexed. Alternatively, the closing of the notch **600** can be provided by reducing the angle of flexibility **106** in comparison to when the notch **600** is not flexed. The opening of the notch **600** can be provided by causing the sides defined by the outer width (**604**, **604A**, or **604B**) of the notch **600** to at least be further to one another than when not flexed. Alternatively, the opening of the notch **600** can be provided by increasing the angle of flexibility **106** in comparison to when the notch **600** is not flexed. Alternately, the different flexibility in the first and second directions of flexibility **102**, **104**, can come from different shaped notches **600**, as above.

The variations in flexibility can translate to the amount of deflection of the distal end **560** of the flexible distal shaft **500**.

FIGS. 2A and 2B illustrate side views of the steerable catheter, the potential flexibility within the first direction of flexibility and the second direction of flexibility, and the method of steering a steerable catheter. The flexible distal shaft **500** can have increased flexibility in the first direction of flexibility **102**. The flexible distal shaft **500** can have decreased flexibility in the second direction of flexibility **104**. The method of steering a steerable catheter **700** enables the rotating of the steerable catheter **100** to alter the first direction of flexibility **102** and second direction of flexibility **104** depending on the preferred orientation. In one example, the label **202** can provide guidance to the user as to which radial direction corresponds to the one or more directions of flexibility **102**, **104**. As the user advances the catheter **100**, rotating the proximal hub **200** can orient the flexible distal shaft **500** toward the chosen direction to advance into a particular fork or branch of the vasculature or desired direction of travel.

In addition, one of the layers **502**, **504**, **506**, **510** can include a radiopaque element to facilitate the identification of the first direction of flexibility **102** and/or the second direction of flexibility **104** or the first primary direction of flexibility **140**, the second primary direction of flexibility **142** or the first secondary direction of flexibility **150** and the second secondary direction of flexibility **152**. In one example, the outer layer **506** has the radiopaque element.

FIG. 3 illustrates a side view of the steerable catheter flexed in the first direction of flexibility illustrating the ability to orient the steerable catheter in the desired direction of travel. The flexible distal shaft **500** can be flexed at a number of angles, including the depicted orthogonal angle, in the first direction of flexibility **102**. The flexible distal shaft **500** can be flexed to facilitate the steerable catheter **100** to advance in the desired direction of travel **110**. In one example, the first direction of flexibility **102** can be provided by closing a subset of the notches **600** while the second direction of flexibility **104** can be provided by opening a subset of notches **600**. The closing of a subset of the notches **600** can be provided by causing the sides defined by the outer width (**604**, **604A**, or **604B**) of a specific notch **600** to touch or at least be closer to one another than when not flexed. Alternatively, the closing of the notch **600** can be provided by reducing the angle of flexibility **106** in comparison to when the notch **600** is not flexed. The opening of a subset of the notches **600** can be provided by causing the sides defined by the outer width (**604**, **604A**, or **604B**) of a specific notch **600** to at least be further to one another than when not flexed. Alternatively, the opening of the notch **600** can be provided by increasing the angle of flexibility **106** in comparison to when the notch **600** is not flexed.

FIGS. 4A and 4B illustrate a side view of the method of steering the steerable catheter into a desired vessel branch. The steerable catheter **100** can be located in a primary vessel **130** with a first direction of flexibility **102** oriented perpendicular to the desired direction of travel **110**. The steerable catheter **100** can be rotated by the method of steering a steerable catheter **700** to orient the first direction of flexibility **102** in the direction of the desired vessel branch **120**. The steerable catheter **100** can be advanced in the desired direction of travel **110** such that the first direction of flexibility **102** enables the steerable catheter **100** to more easily advance into the desired vessel branch **120**.

FIGS. 5A and 5B illustrate the notches of the flexible distal shaft and their orientation when flexed in the direction

of the first direction of flexibility. The flexible distal shaft **500** can have the first direction of flexibility **102** oriented in the direction of the desired vessel branch **120**. FIG. **5B** depicts a close-up of the flexible distal shaft and the notches. The notches **600** can be oriented in the first direction of flexibility **102**. The notches **600** can form an angle of flexibility **106**. The notches **600** can determine the flexibility of the steerable catheter **100** in the direction of the first direction of flexibility **102**.

FIGS. **6A** and **6B** illustrate a side view of the method of locking a steerable catheter. The method of locking a steerable catheter **800** can include rotating a flexible distal shaft **500** at the proximal hub **200** to orient the first direction of flexibility **102** such that the flexible distal shaft **500** contacts a wall of the vessel branch **122** to limit the movement of the flexible distal shaft **500** in the desired direction of travel **110**. FIG. **6B** depicts a close-up side view of the notches and their orientation with respect to the vessel branches. The method of locking a steerable catheter **800** can include rotating a flexible distal shaft **500** at the proximal hub **200** orienting the notches **600** which are oriented in the same direction as the first direction of flexibility **102**.

An example of locking can be entering the desired branch vessel **120** using the first direction of flexibility **102** to bend the distal flexible shaft **500** to “make the turn” into the branch. This is illustrated in FIGS. **5A** and **5B** and as illustrated the first direction of flexibility **102** is directed to the “inside” of the curve. The user then torques or rotates the catheter **100** so that the first direction of flexibility **102** is opposed to the “inside,” as illustrated in FIGS. **6A** and **6B**. The distal flexible shaft **500** is now more “stiff” as the second direction of flexibility **104** faces the “inside” of the curve. Less flexibility can translate to the distal end **560** of the distal shaft **500** not being able to make the turn as “sharp” as if it was more flexible. This now moves the flexible distal shaft **500** to contact the “outside” wall of the vessel, “locking” the catheter **100** into place. Locking the catheter **100** can be beneficial during certain procedures to allow for retrieval or deployment of elements in and out of the lumen **108**.

FIG. **7A** illustrates a side view of a steerable catheter with notches with two different orientations. The steerable catheter **100** can include notches with multiple, different orientations. For example, one set of notches is oriented in the direction of the first primary direction of flexibility **140** and the second primary direction of flexibility **142**. One set of notches is oriented in the direction of the first secondary direction of flexibility **150** and the second secondary direction of flexibility **152**.

FIGS. **7B** and **7C** illustrate cross-section views of the steerable catheter as depicted in FIG. **7**. The steerable catheter **100** can have an inner layer **502**, a segmented mid-layer with different oriented notches **510**, and an outer layer **506**. FIG. **7B** illustrates the segmented mid-layer with different oriented notches **510** can have a primary notch **610** oriented to enable flexibility in the first primary direction of flexibility **140**. FIG. **7C** illustrates the segmented mid-layer with different oriented notches **510** can have a secondary notch **620** oriented to enable flexibility in the first secondary direction of flexibility **150**.

FIG. **7D** illustrates the primary notch **610** in the segmented mid-layer **510**. For example, the primary notch **610** having a depth **612**, an outer width **614** and an inner width **616**. The depth **612**, outer width **614**, and inner width **616** can relate to the flexibility in the first primary direction of

flexibility **140**. The depth **612**, outer width **614**, and inner width **616** can relate to the flexibility in the second primary direction of flexibility **142**.

FIG. **7E** illustrates the secondary notch **620** in the segmented mid-layer **510**. For example, the secondary notch **620** having a depth **622**, an outer width **624**, and an inner width **624**. The depth **622**, outer width **624**, and inner width **626** can relate to the flexibility in the first secondary direction of flexibility **150**. The depth **622**, outer width **624**, and inner width **626** can relate to the flexibility in the second secondary direction of flexibility **152**.

FIG. **8A** illustrates a side view of the steerable catheter with notches with two different orientations. The steerable catheter **100** can have a segmented mid-layer with different oriented notches **510** such that the steerable catheter **100** has flexibility in the first primary direction of flexibility **140** and the first secondary direction of flexibility **150**. FIGS. **8B** and **8C** depict close-up side views of the primary and secondary notches and their orientation with respect to the first and second primary directions of flexibility. The steerable catheter **100** can have a primary notch **610** enabling flexibility in the first primary direction of flexibility **140** and a primary angle of flexibility **144**. The steerable catheter **100** can have a secondary notch **620** enabling flexibility in the second primary direction of flexibility **150** and a secondary angle of flexibility **154**.

In examples, the first primary direction of flexibility **140** can be provided by closing a subset of the primary notches **610** while the second primary direction of flexibility **142** can be provided by opening a subset of the primary notches **610**. The closing of a subset of the primary notches **610** can be provided by causing the sides defined by the outer width **614** of a specific primary notch **610** to touch or at least be closer to one another than when not flexed. Alternatively, the closing of a primary notch **610** can be provided by reducing the primary angle of flexibility **144** in comparison to when the primary notch **610** is not flexed. The opening of a subset of the primary notches **610** can be provided by causing the sides defined by the outer width **614** of a specific primary notch **610** to at least be further to one another than when not flexed. Alternatively, the opening of the primary notch **610** can be provided by increasing the primary angle of flexibility **144** in comparison to when the primary notch **610** is not flexed.

In examples, the second primary direction of flexibility **150** can be provided by closing a subset of the secondary notches **620** while the second secondary direction of flexibility **152** can be provided by opening a subset of the secondary notches **620**. The closing of a subset of the secondary notches **620** can be provided by causing the sides defined by the outer width **624** of a specific secondary notch **620** to touch or at least be closer to one another than when not flexed. Alternatively, the closing of a secondary notch **620** can be provided by reducing the secondary angle of flexibility **154** in comparison to when the secondary notch **620** is not flexed. The opening of a subset of the secondary notches **620** can be provided by causing the sides defined by the outer width **624** of a specific secondary notch **620** to at least be further to one another than when not flexed. Alternatively, the opening of the secondary notch **620** can be provided by increasing the secondary angle of flexibility **154** in comparison to when the secondary notch **620** is not flexed.

FIG. **9** is a flow diagram outlining example method steps that can be carried out to steer a steerable catheter. The method steps can be implemented by any of the example

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means described herein or by any means that would be known to one of ordinary skill in the art.

Referring to a method **700** outlined in FIG. **9**, in step **710** a steerable catheter **100** can be provided. In step **720**, the steerable catheter **100** can be rotated. In step **730**, the flexible distal shaft **500** of the steerable catheter **100** can be oriented in the preferred direction. In step **740**, the steerable catheter **100** can be advanced in the desired direction of travel **110** benefitting from the orientation of the flexible distal shaft **500** and its first direction of flexibility **102**.

FIG. **10** is a flow diagram outlining example method steps that can be carried out to lock a steerable catheter. The method steps can be implemented by any of the example means described herein or by any means that would be known to one of ordinary skill in the art.

Referring to a method **800** outlined in FIG. **10**, in step **810** a steerable catheter **100** can be provided. In step **820**, the steerable catheter **100** can be rotated. In step **830**, the flexible distal shaft **500** of the steerable catheter **100** can be oriented in the preferred direction. In step **840**, the steerable catheter **100** can be advanced in the desired direction of travel **110** benefitting from the orientation of the flexible distal shaft **500** and its first direction of flexibility **102**. In step **850**, the steerable catheter **100** can be rotated pursuant to the method of steering a steerable catheter **700** to orient the flexible distal shaft **500** first direction of flexibility **102** such that the flexible distal shaft **500** contacts a wall of vessel branch **122** to limit movement of the flexible distal shaft in the desired direction of travel **110**.

The descriptions contained herein are examples of embodiments of the invention and are not intended in any way to limit the scope of the invention. As described herein, the invention contemplates many variations and modifications of the . . . device, including . . . . These modifications would be apparent to those having ordinary skill in the art to which this invention relates and are intended to be within the scope of the claims which follow.

The invention claimed is:

**1.** A steerable catheter comprising:

a flexible distal shaft comprising:

a proximal end;

a distal end;

a first direction of flexibility;

a second direction of flexibility opposite to the first direction of flexibility;

an inner layer;

a segmented mid-layer comprising:

a plurality of notches on an outer surface of the mid-layer, the plurality of notches comprising a first depth, a first outer width, and a first inner width;

wherein the first depth, the first outer width, and the first inner width are related to an angle of flexibility; and

wherein the first outer width is greater than the first inner width;

wherein the plurality of notches are configured to bend in the first direction of flexibility;

wherein a first subset of the plurality of notches on the outer surface of the mid-layer comprise a second depth, a second outer width, and a second inner width;

wherein the second depth is different from the first depth, the second outer width is different from the first outer width, and the second inner width is different from the first inner width; and

wherein the first subset of the plurality of notches is configured to bend in the first direction of flexibility;

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wherein a second subset of the plurality of the notches on the outer surface of the mid-layer comprise a third depth, a third outer width, and a third inner width, wherein the third depth is different from the first depth and the second depth, the third outer width is different from the first outer width and the second outer width, and the third inner width is different from the first outer width and the second outer width; and

an outer layer;

wherein a flexibility of the flexible distal shaft is greater in the first direction of flexibility than any other direction.

**2.** The steerable catheter of claim **1**, wherein the plurality of notches are a first geometric shape.

**3.** The steerable catheter of claim **2**, wherein the first subset of the plurality of the notches comprise at least one of a second geometric shape.

**4.** The steerable catheter of claim **3**, wherein the second subset of the plurality of the notches comprise at least one of a third geometric shape.

**5.** The steerable catheter of claim **1**, wherein the segmented mid-layer is configured to resist bending in the second direction of flexibility.

**6.** The steerable catheter of claim **1**, wherein the outer layer is elastic.

**7.** The steerable catheter of claim **1**, further comprising: an intermediate shaft comprising a proximal end and a distal end wherein the distal end of the intermediate shaft is connected to the proximal end of the flexible distal shaft;

a proximal shaft comprising a proximal end and a distal end, wherein the distal end of the proximal shaft is connected to the proximal end of the intermediate shaft; and

a proximal hub comprising a proximal end and a distal end, wherein the distal end of the proximal hub is connected to the proximal end of the proximal shaft.

**8.** The steerable catheter of claim **7**, wherein:

the proximal shaft comprises a proximal shaft flexibility; the intermediate shaft comprises an intermediate shaft flexibility;

the flexibility of the flexible distal shaft is greater than the intermediate shaft flexibility;

the flexibility of the flexible distal shaft is greater than the proximal shaft flexibility;

the flexibility of the intermediate shaft is greater than the proximal shaft flexibility; and

a change in flexibility from the proximal shaft flexibility to the intermediate shaft flexibility to the flexibility of the flexible distal shaft allows a torque to be transmitted along a length of the catheter.

**9.** The steerable catheter of claim **7**, wherein the proximal hub comprises a label to indicate the first direction of flexibility of the steerable catheter.

**10.** The steerable catheter of claim **1**, wherein the outer layer comprises a radiopaque element to determine the first direction of flexibility.

**11.** The steerable catheter of claim **1**, wherein the second depth is greater than the first depth, the second outer width is greater than the first outer width, and the second inner width is greater than the first inner width.

**12.** The steerable catheter of claim **1**, wherein the third depth is less than the first depth and the second depth, the third outer width is less than the first outer width and the second outer width, and the third inner width is less than the first outer width and the second outer width.



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13. A steerable catheter comprising:  
 a flexible distal shaft comprising:  
 a proximal end;  
 a distal end;  
 a first direction of flexibility;  
 a second direction of flexibility opposite to the first  
 direction of flexibility;  
 an inner layer;  
 a segmented mid-layer comprising:  
 a plurality of notches on an outer surface of the  
 mid-layer, the plurality of notches comprising a first  
 depth, a first outer width, and a first inner width;  
 wherein the first depth, the first outer width, and the  
 first inner width are related to an angle of flexibility;  
 and  
 wherein the first outer width is greater than the first  
 inner width;  
 wherein the plurality of notches are configured to bend  
 in the first direction of flexibility;  
 wherein a first subset of the plurality of notches on the  
 outer surface of the mid-layer comprise a second  
 depth, a second outer width, and a second inner  
 width;  
 wherein the second depth is different from the first  
 depth, the second outer width is different from the  
 first outer width, and the second inner width is  
 different from the first inner width; and  
 wherein the first subset of the plurality of notches is  
 configured to bend in the first direction of flexibility;  
 wherein a second subset of the plurality of the notches  
 on the outer surface of the mid-layer comprise a third  
 depth, a third outer width, and a third inner width,  
 wherein the third depth is different from the first depth  
 and the second depth, the third outer width is dif-  
 ferent from the first outer width and the second outer  
 width, and the third inner width is different from the  
 first outer width and the second outer width; and  
 an outer layer;  
 wherein a flexibility of the flexible distal shaft is greater  
 in the first direction of flexibility than any other direc-  
 tion, and  
 wherein the third depth is less than the first depth and the  
 second depth, the third outer width is less than the first

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outer width and the second outer width, and the third  
 inner width is less than the first outer width and the  
 second outer width.

14. The steerable catheter of claim 13, wherein the  
 plurality of notches are a first geometric shape.

15. The steerable catheter of claim 14, wherein the first  
 subset of the plurality of the notches comprise at least one  
 of a second geometric shape.

16. The steerable catheter of claim 15, wherein the second  
 subset of the plurality of the notches comprise at least one  
 of a third geometric shape.

17. The steerable catheter of claim 13, wherein the  
 segmented mid-layer is configured to resist bending in the  
 second direction of flexibility.

18. The steerable catheter of claim 13, further comprising:  
 an intermediate shaft comprising a proximal end and a  
 distal end wherein the distal end of the intermediate  
 shaft is connected to the proximal end of the flexible  
 distal shaft;

a proximal shaft comprising a proximal end and a distal  
 end, wherein the distal end of the proximal shaft is  
 connected to the proximal end of the intermediate shaft;  
 and

a proximal hub comprising a proximal end and a distal  
 end, wherein the distal end of the proximal hub is  
 connected to the proximal end of the proximal shaft.

19. The steerable catheter of claim 18, wherein:  
 the proximal shaft comprises a proximal shaft flexibility;  
 the intermediate shaft comprises an intermediate shaft  
 flexibility;

the flexibility of the flexible distal shaft is greater than the  
 intermediate shaft flexibility;

the flexibility of the flexible distal shaft is greater than the  
 proximal shaft flexibility;

the flexibility of the intermediate shaft is greater than the  
 proximal shaft flexibility; and

a change in flexibility from the proximal shaft flexibility  
 to the intermediate shaft flexibility to the flexibility of  
 the flexible distal shaft allows a torque to be transmitted  
 along a length of the catheter.

20. The steerable catheter of claim 13, wherein the second  
 depth is greater than the first depth, the second outer width  
 is greater than the first outer width, and the second inner  
 width is greater than the first inner width.

\* \* \* \* \*